

6 August 2020
[131–20]

Call for submissions – Application A1180

Natural Glycolipids as a preservative in non-alcoholic beverages

FSANZ has assessed an Application made by LANXESS Deutschland GmbH to permit the use of a long-chain glycolipid mixture derived from an edible jelly fungus. The glycolipid mixture is referred to by its descriptive name ‘jelly mushroom Glycolipids’ and is proposed to be used as a preservative in non-alcoholic beverages. As such, FSANZ has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word ‘Submission’ and quote the correct project number and name (A1180 - Natural Glycolipids as a preservative in non-alcoholic beverages). While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 17 September 2020

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting document

The [following document](#)¹ which informed the assessment of this Application are available on the FSANZ website:

SD1 Risk and Technical Assessment Report – Application A1180

¹ <https://www.foodstandards.gov.au/code/applications/Pages/A1180.aspx>

Executive summary

FSANZ has assessed an application from LANXESS Deutschland GmbH to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of a long-chain glycolipid mixture derived from an edible jelly fungus (jelly mushroom glycolipids) for use as a food additive (preservative) in non-alcoholic beverages.

The application seeks permission for the following maximum permitted levels of jelly mushroom glycolipids to be permitted in the associated non-alcoholic beverages categories

1. 100 mg/kg for Fruit and vegetable juices and fruit and vegetable juice products
2. 50 mg/kg for Water based flavoured drinks;
3. 20 mg/kg for Formulated Beverages;
4. 10 mg/kg for Coffee, coffee substitutes, tea, herbal infusions and similar products;
5. 100 mg/kg for non-alcoholic beer.

Jelly mushroom glycolipids function as a preservative against common yeasts and moulds in non-alcoholic beverages.

Based on FSANZ's hazard assessment, an acceptable daily intake (ADI) of 2.0 mg/kg body weight per day has been established. Dietary exposures estimated by FSANZ were below this ADI and therefore it was concluded that there are no public health and safety concerns from the use of jelly mushroom glycolipids at the proposed levels in the non-alcoholic beverage categories mentioned above.

Based on the FSANZ food technology assessment, the use of jelly mushroom glycolipids as a food additive in the quantity and form proposed is technologically justified. It is appropriately classified as a food additive since it provides a technological function as a preservative.

There is currently no specification for jelly mushroom glycolipids in the Code, nor are there any relevant international standards. Jelly mushroom glycolipids do however have a generally recognised as safe (GRAS) status in the U.S.A. As such, FSANZ has drafted a potential specification for jelly mushroom glycolipids to be included in Schedule 3 of the Code.

FSANZ has considered the potential impacts of approving a draft variation to the Code and has concluded that the direct and indirect benefits that would arise from permitting jelly mushroom glycolipids most likely outweighs the associated costs.

FSANZ has therefore prepared a draft variation to permit the use of jelly mushroom glycolipids as a food additive in the requested non-alcoholic beverage categories at the permitted levels sought.

1 Introduction

1.1 The Applicant

LANXESS Deutschland GmbH is a company whose core business is the development, manufacture and marketing of chemical intermediates, additives, specialty chemicals and plastics.

1.2 The Application

The purpose of the application is to amend the Code to permit the use of long-chain glycolipids from *Dacryopinax spathularia* (Jelly mushroom glycolipids) as a food additive for the purposes of preserving non-alcoholic beverages. The application is seeking permission for jelly mushroom glycolipids at levels ranging between 2 to 100 mg/kg for different non-alcoholic beverage categories².

Jelly mushroom Glycolipids are considered by the applicant to have antifungal effects against common yeasts, moulds as well as antimicrobial effects against bacteria, and can be used to prolong the shelf life of non-alcoholic beverages. They may be used as an alternative in some instances to existing preservatives, as well as being used alongside existing production practices (e.g. heat treatment) to preserve beverages.

1.3 The current standards

Australian and New Zealand food laws require food for sale to comply with the following Code requirements.

1.3.1 Permitted use

Jelly mushroom glycolipids are not currently permitted to be added to non-alcoholic beverages as a food additive – preservative.

1.3.2 Food additive permissions

Paragraph 1.1.1—10(6)(a) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance ‘used as a food additive’ unless that substance’s use as a food additive is expressly permitted by the Code.

Section 1.3.1—3 details which substances are permitted to be used as a food additive for the purposes of the Code. The permitted food additives for different food categories are listed in the table to section S15—5 of the Code.

Section 1.1.2—11 also provides that a substance is ‘used as a food additive’ if it is added to a food to perform one or more technological functions listed in Schedule 14 of the Code and is a substance identified in the table to section S15—5 as a permitted food additive.

Schedule 14 lists the permitted technological purposes of food additives. The table to section S14—2 provides that use as a preservative is a permitted technological purpose.

Schedule 15 lists the specific food additive permissions for different classes of food products. Item 14.1.2 in the table to section S15—5 lists the permitted food additives for Fruit and vegetable juices and fruit and vegetable juice products. Item 14.1.3 in the table to section

² Non-alcoholic beverage categories: Fruit and vegetable juices and fruit and vegetable juice products, Water based flavoured drinks, Formulated Beverages, Coffee, coffee substitutes, tea, herbal infusions and similar products, and non-alcoholic beer.

S15—5 lists the permitted food additives for Water based flavoured drinks. Item 14.1.4 in the table to section S15—5 lists the permitted food additives for Formulated Beverages. Item 14.1.5 in the table to section S15—5 lists the permitted food additives for Coffee, coffee substitutes, tea, herbal infusions and similar products. Item 14.2.1 in the table to section S15—5 lists the permitted food additives for Beer and related products (including alcoholic beverages that have had the alcohol reduced or removed).

1.3.3 Labelling

Paragraph 1.1.1—10(8) of the Code provides that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Standard 1.2.4 of the Code generally requires food products to be labelled with a statement of ingredients. Subsection 1.2.4—7(1) of that Standard requires most food additives to be declared in the statement of ingredients by either specifying the class name followed by the name of the substance or code number in brackets or the name of the substance as indicated in Schedule 8.

Schedule 7 (Food additive class names (for statement of ingredients)) lists prescribed food additive class names. 'Preservative' is a prescribed class name.

Schedule 8 (for statement of ingredients) lists the names and code numbers of food additives that are to be used for labelling purposes.

Schedule 8 does not refer to glycolipids from *Dacryopinax spathularia* as this substance is not currently permitted to be added to food as a food additive.

1.3.4 Identity and purity requirements

Food additives permitted by section 1.3.1 and Schedule 15 must also meet any relevant identity and purity specifications set out in Schedule 3. Section S3—4 of schedule 3 outlines that if there are no relevant secondary specification under S3—2 or S3—3 any subsequent specification in the Code must not contain more than; 2 mg/kg of lead, 1 mg/kg of arsenic, 1 mg/kg of cadmium, or 1 mg/kg of mercury.

Given the specification of jelly mushroom glycolipids outlined in the Supporting Document associated with this Call for Submissions, jelly mushroom glycolipids meet these heavy metal limit requirements under schedule 3.

1.3.5 International standards

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex). Standards set by Codex provide a benchmark against which national food measures and regulations can be assessed. In certain situations however, FSANZ might receive an application to amend the Code for permission to use a new food additive before an international standard exists.

In this circumstance there are no international standards concerning the use of jelly mushroom glycolipids as a food additive. However, the substance is currently permitted for use in the USA where it has been determined as Generally Recognized as Safe (GRAS).

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the Food Standards Australia New Zealand Act 1991 (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure
- it was not so similar to a previous Application for the variation of a food regulatory measure that it ought to be rejected.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

A risk assessment was conducted (see Supporting Document 1) to assess the safety and efficacy of jelly mushroom glycolipids. The following are the main findings from the risk assessment.

2.1.1 Food technology assessment

FSANZ concludes that the use of jelly mushroom glycolipids when used as a food additive for preservative purposes is justified. It may serve as an alternative to existing permitted preservatives, or be used in addition to beverage production methods used to reduce spoilage from yeasts, moulds and bacteria. There is currently no specification for jelly mushroom glycolipids in the Code. As such, a proposed specification based on the identification and purity data reviewed by FSANZ is provided in Attachment A under the proposed variation to Schedule 3.

2.1.2 Microbiological assessment

The exact mechanism for the mode of action for the jelly mushroom glycolipids has not been established. However, the results of *in vitro* studies suggest that the surfactant properties of these glycolipids alter the cytoplasmic membrane leading to increased permeability. The metabolism of the cells is affected leading to cell death. Results of *in vitro* studies suggest that there are important differences in the response of microorganisms to jelly mushroom glycolipids. Gram-negative bacteria are the most resistant, followed by Gram-positive bacteria. Challenge studies using defined mixtures of yeasts and moulds highlighted differences between non-alcoholic beverage types. FSANZ concludes that the addition of jelly mushroom glycolipids at the proposed use levels is effective as a preservative against yeasts and moulds in non-alcoholic beverages.

2.1.3 Safety assessment

The submitted data, together with information located from other sources, are considered suitable to assess the hazard of jelly mushroom glycolipids. The Supporting Document alongside this Call for Submissions has further detail regarding the safety assessment.

Pharmacokinetic data indicate that both the parent mixture and the hydrolysis products are likely to be poorly absorbed by the oral route. There was no evidence of persistence or bioaccumulation in any particular tissue. Acute oral toxicity in rats was greater than 2000 mg/kg bodyweight

Short-term repeat-dose Good Laboratory Practice (GLP)-compliant (studies in rats and dogs were submitted. In a 90-day drinking water study in Sprague Dawley rats, no adverse effects

were found at the highest dose administered, equivalent to 1201 and 1423 mg/kg bw/day in male and female rats respectively. In a 90-day oral capsule study in Beagle dogs, a significant reduction, relative to that of controls, in group mean cumulative bodyweight gain in female dogs, with a corresponding but non-significant reduction in group mean food consumption, at 1000 mg/kg bw/day, is considered to be adverse by FSANZ. FSANZ considers that the No Observed Adverse Effect Level (NOAEL) for this study is 500 mg/kg bw/day.

No chronic or carcinogenicity studies of jelly mushroom glycolipids were submitted in the application or located from other sources. Jelly mushroom glycolipids were not genotoxic in GLP-compliant genotoxicity studies that included bacterial reverse mutation assay, micronucleus test in human lymphocytes, and cell gene mutation test (TK mutation test) in L5178Y mouse lymphoma cells. There was an absence of test article related lesions in the repeat-dose studies, and therefore there was no evidence of neoplastic potential by a non-genotoxic mechanism.

Potential for developmental and/or reproductive toxicity was assessed in two GLP-compliant studies in Sprague Dawley rats, a developmental toxicity study and a two-generation reproductive toxicity study. The NOAEL for parental toxicity, embryo/fetal developmental toxicity and toxicity to offspring was the highest dose tested in the two studies, 1000 mg/kg bw/day.

No human tolerance studies of jelly mushroom glycolipids were submitted or located from other sources. It is relevant that the source organism, *Dacryopinax spathularia*, is listed in the FAO compendium on edible mushrooms and is described as edible in peer-reviewed publications from a range of countries in multiple continents. There are no case reports of allergic reactions to the source organism, or evidence of allergenic potential of jelly mushroom glycolipids. There is a lack of evidence that glycolipids act as food allergens.

The ADI is derived from the lowest NOAEL identified in animals, 500 mg/kg bw/day in Beagle dogs. FSANZ has applied an uncertainty factor of 10 for extrapolation from animals to humans, an uncertainty factor of 10 for variability between humans, and an uncertainty factor of 3 allowing for extrapolation from a subchronic study to chronic exposure, for a total uncertainty factor of 300. An uncertainty factor of 3, rather than 10, has been selected because there is a clear NOAEL at 500 mg/kg bw/day, and the effect is minimal at twice that value, although the dogs were at an age when growth is rapid and energy requirement is high. The ADI is established by division of the lowest NOAEL (500 mg/kg bw/day) by the total UF (300), approximately equalling 1.6, and rounded to 2.0 mg/kg bw/day.

In conclusion, FSANZ has identified an ADI of 2.0 mg/kg bw/day, based on decreased bodyweight gain in growing dogs.

2.1.4 Dietary exposure assessment

The dietary exposure assessment for jelly mushroom glycolipids assessed additive uses across three scenarios; *General MPL*³, *Specific MPL* and *Usual Use* levels and for three population groups; Australians aged 2 years and above, New Zealanders aged 15 years and above and New Zealand children aged 5-14 years. The assessment showed that mean and 90th percentile (P90) estimated dietary exposures for all scenarios and population groups assessed fell below the ADI of 2.0 mg/kg bw/day. The mean dietary exposures ranged between 10-35% of the ADI and P90 dietary exposures ranged between 20-75% of the ADI.

Across all population groups assessed and all scenarios, the two major contributing food categories to jelly mushroom glycolipids dietary exposures were: 1) Water based flavoured

³ Maximum Permitted Level.

drinks, excluding powders, iced teas, brewed soft drinks; and 2) Fruit and vegetable juices.

The Consumer dietary exposures to jelly mushroom glycolipids for Australians aged 2 years and above (mean: 0.46 mg/kg bw/day; P90: 1.0 mg/kg bw/day) and New Zealander aged 15 years and above (mean: 0.38 mg/kg bw/day; P90: 0.87 mg/kg bw/day) are similar to those estimated for American consumers (mean: 0.51 mg/kg bw/day; P90: 1.09 mg/kg bw/day) in the US GRAS notification (US FDA, 2017)⁴.

2.2 Risk management

Given the findings of the safety assessment, FSANZ considers an ADI of 2.0 mg/kg bw/day appropriate. It is noted the dietary exposure assessment indicates the requested levels of jelly mushroom glycolipids sought by the applicant to be permitted in different categories of non-alcoholic beverages would not exceed the proposed ADI. Furthermore, while the mode of action that allows the jelly glycolipids to inhibit mould and yeasts in beverages is not completely understood, it none the less shows a degree of efficacy in extending non-alcoholic beverage shelf life at the proposed levels of addition (2-100 mg/kg), with no public health and safety concerns being identified.

The risk management options available to FSANZ after assessment were to: reject the application; or prepare a draft variation to amend the Code to permit jelly mushroom glycolipids as a food additive in non-alcoholic beverages at the requested levels for different non-alcoholic beverage categories. Based on the risk assessment, the decision was made to prepare a draft variation to the Code (Attachment A).

2.2.1 Labelling

Food additives must be listed in the statement of ingredients in accordance with requirements set out in section 1.2.4—7 of the Code. This application seeks permission to use glycolipids from jelly mushroom fungus as a preservative in non-alcoholic beverages. Glycolipids from *Dacryopinax spathularia* (a jelly mushroom fungus) does not yet have a number in the Codex Alimentarius International Numbering System (INS) for food additives.

The applicant has proposed 'natural glycolipids' as a possible name for glycolipids from jelly mushroom fungus for labelling purposes. FSANZ considers 'natural glycolipids' is not sufficiently specific given the three main glycolipids in the glycolipid mixture from jelly mushroom fungus are not found in other foods (SD1). Therefore, the name 'jelly mushroom glycolipids' is proposed so the glycolipid source is clearly identified. This name is one of four names listed in the GRAS notification⁵ that can be used for labelling purposes in the USA.

Accordingly, based on current Code requirements for additive labelling and the absence of an INS number, the presence of glycolipids from jelly mushroom fungus in a food would need to be declared in the statement of ingredients using either the class name 'preservative' followed by 'jelly mushroom glycolipids' in brackets or 'jelly mushroom glycolipids'. Should an INS number be assigned in the future, this could be added to Schedule 8.

The Code does not define or regulate the use of the word 'natural'. Such a descriptor can be used voluntarily by food businesses and is subject to fair trading laws in Australia and New Zealand which prohibit representations about food that are, or are likely to be, false,

⁴ US FDA (2017) GRAS Notice (GRN) No. 740: GRAS Notification for Long-Chain Glycolipids from *Dacryopinax spathularia*. Accessed 3 June 2020. <https://www.fda.gov/media/113331/download>

⁵ The four names listed in the GRAS notification are: jelly mushroom glycolipids, sweet osmanthus ear glycolipids, *Cantharellus spathularius* ferment extract, mushroom ferment extract (*Dacryopinax spathularia*).

misleading or deceptive.

There are some exemptions to the above requirements for the statement of ingredients for foods for sale that are not required to bear a label. These exemptions are set out in section 1.2.1—6 of the Code, and include foods made and packaged on the premises from which it is sold and foods packaged in the presence of the purchaser.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process.

FSANZ developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the Food Standards Notification Circular, media release, through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no Codex standards concerning the use of jelly mushroom glycolipids as a food additive in non-alcoholic beverages. Other than having GRAS status⁶ in the U.S.A, there are currently no other national standards or regulations approving the use of jelly mushroom glycolipids, although dossiers for approval in the EU and Canada are in preparation by the applicant.

Amending the Code to permit jelly mushroom glycolipids as a food additive in non-alcoholic beverages is unlikely to have a significant effect on international trade given its use as a food additive is voluntary and the proposed amendment to the Code would not conflict with existing or standards. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

2.4.1 Section 29

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting new food additives

⁶ <https://www.fda.gov/media/113331/download>

(OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting food additives is machinery in nature as they are part of implementing a regulatory framework where the use of the new additive is voluntary once the application has been approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (S.29 (2)(a)).

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where the status quo is rejecting the application). This analysis considers permitting jelly mushroom glycolipids as a food additive. FSANZ is of the view that no other realistic food regulatory measures exist, however information received may result in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the additive.

Costs and benefits of permitting jelly mushroom glycolipids as a food additive

Jelly mushroom glycolipids are considered by the Applicant and FSANZ's assessment to have antifungal effects against common yeasts and moulds and can be used to prolong the shelf life of non-alcoholic beverages. They may be used as an alternative in some instances to existing preservatives, as well as being used alongside existing production practices (e.g. heat treatment) to preserve beverages.

Due to the voluntary nature of the permission, industry will only use the food additive where they believe a net benefit exists. Industry will benefit from having additional processing choices available to them.

The food additive is permitted as a preservative in the USA which may be a trade opportunity for Australia and New Zealand businesses, although there may also be competing imports from the USA into the domestic market.

Permitting jelly mushroom glycolipids may result in a small cost to government in terms of adding it to the current range of food additives that are monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting jelly mushroom glycolipids as a food additive in non-alcoholic drinks most likely outweigh the associated costs.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.

2.4.1.3 Any relevant New Zealand standards

The proposed amended Standards in question apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ has completed a hazard and dietary exposure assessment (SD1) which is summarised in section 4.4. The hazard assessment concluded there are no public health and safety concerns in permitting jelly mushroom glycolipids as a food additive in non-alcoholic beverages at an Acceptable Daily Intake (ADI) of 2.0 mg/kg of body weight per day. The Dietary exposure assessment in section 5 of SD1 indicates this ADI would not be exceeded at the requested levels for jelly mushroom glycolipids being added to the various non-alcoholic beverage categories.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The labelling requirements for jelly mushroom glycolipids used as a preservative are discussed in section 2.2.1. These requirements provide information to enable consumers to make informed food choices.

2.4.2.3 The prevention of misleading or deceptive conduct

No issues have been identified within this application that are relevant to this objective under the FSANZ Act.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has used the best available scientific evidence to conduct the food technology, hazard and dietary exposure assessment (SD1). The applicant submitted supporting information, including scientific studies, product information and relevant literature, as part of their application. FSANZ also considered other information relevant to the application (referenced in the document and reference list).

- **the promotion of consistency between domestic and international food standards**

Jelly mushroom glycolipids are GRAS in the USA for the preservative purpose proposed (GRN 740)⁷. The Applicant is reportedly in the process of seeking permissions for the use of

⁷ US FDA (2017) GRAS Notice (GRN) No. 740: GRAS Notification for Long-Chain Glycolipids from *Dacryopinax spathularia*. Accessed 3 June 2020. <https://www.fda.gov/media/113331/download>

jelly mushroom glycolipids in the European Union.

- **the desirability of an efficient and internationally competitive food industry**

Permitting this food additive gives the applicant and producers of non-alcoholic beverages the opportunity to use an alternative preservative to avoid beverage spoilage caused by moulds and yeasts.

- **the promotion of fair trading in food**

FSANZ did not identify any relevant issues relating to this consideration.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The Ministerial Policy Guideline for [Addition to Food of Substances other than Vitamins and Minerals](#)⁸ includes specific order policy principles for substances added to achieve a solely technological function, such as food additives. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose'),
- the addition of the substance to food is safe for human consumption,
- the amounts added are consistent with achieving the technological function,
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose, and
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ has determined that permitting jelly mushroom glycolipids as a food additive for a preservative technological function is consistent with the Ministerial Policy Guideline.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

4 References

US FDA (2017) GRAS Notice (GRN) No. 740: GRAS Notification for Long-Chain Glycolipids from *Dacryopinax spathularia*. Accessed 3 June 2020. <https://www.fda.gov/media/113331/download>

Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

⁸ <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals>

Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1180 – Natural Glycolipids as a preservative in non-alcoholic beverages) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

[Name of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1180 – Natural Glycolipids as a preservative in non-alcoholic beverages) Variation*.

2 Variation to standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] **Schedule 2** is varied by inserting in the table to section S2—2 in alphabetical order

MPN	most probable number
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[2] **Schedule 3** is varied by

[2.1] inserting in the table to subsection S3—2(2) in alphabetical order

jelly mushroom glycolipids	section S3—43
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[2.2] inserting after section S3—42

S3—43 Specification for jelly mushroom glycolipids

For jelly mushroom glycolipids, the specifications are the following:

- (a) CAS number—2205009-17-0;
- (b) chemical structure—a mixture of long-chain glycolipids obtained from the fermentation and filtration of the non-GMO *Dacryopinax spathularia* strain MUCL 53181;
- (b) description—off-white to ivory powder;
- (c) pH—between 5.0 and 7.0 (1% aqueous solution);
- (d) water—less than 5%;
- (e) protein—less than 3%;
- (f) fat—less than 2%;
- (g) total glycolipid content on a dry weight basis for the powder—no less than 93%;
- (h) lead—not more than 2 mg/kg;
- (i) arsenic—not more than 1 mg/kg;
- (j) cadmium— not more than 1 mg/kg;
- (k) mercury— not more than 1 mg/kg;
- (l) microbial limits:
 - (i) total aerobic microbial count—not more than 100 cfu/g;
 - (ii) total yeast and mould count—not more than 10 cfu/g;
 - (iii) coliforms—not more than 3 MPN/g;
 - (iv) *Escherichia coli*—not more than 3 MPN/g.

[3] **Schedule 8** is varied by

[3.1] inserting in the table to section S8—2 entitled 'Food additive names—alphabetical listing', in alphabetical order

Jelly mushroom glycolipids	—
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[3.2] inserting in the table to section S8—2 entitled 'Food additive names—numerical listing', above the entry for 'Monk fruit extract or luo han guo extract'

– Jelly mushroom glycolipids

[4] Schedule 15 is varied by

[4.1] inserting in item 14.1.2 of the table to section S15–5, after the heading 'Fruit and vegetable juices and fruit and vegetable juice products'

Jelly mushroom glycolipids 100

[4.2] inserting in item 14.1.3 of the table to section S15–5, after the entry for 'Colourings permitted to a maximum level'

Jelly mushroom glycolipids 50

[4.3] inserting in item 14.1.4 of the table to section S15–5, after the entry for 'Colourings permitted to a maximum level'

Jelly mushroom glycolipids 20

[4.4] inserting in item 14.1.5 of the table to section S15–5, after the entry for 'Additives permitted at GMP'

Jelly mushroom glycolipids 10

[4.5] inserting in item 14.2.1 of the table to section S15–5, after the heading 'Beer and related products'

Jelly mushroom glycolipids 100 Only beer where the alcohol has been removed

Attachment B – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1180 which seeks to permit the use of long-chain glycolipids from *Dacryopinax spathularia* (jelly mushroom glycolipids) to be used as a food additive in non-alcoholic beverages. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft Standard.

2. Purpose

The Authority has prepared a draft variation to the Code to permit jelly mushroom glycolipids as a food additive in non-alcoholic beverages at a maximum permitted level specified in Schedule 15 (depending on the beverage category).

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1180 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated assessment summary.

A Regulation Impact Statement was not required because the proposed variations to Schedules 2, 3, 8 and 15, if approved, would be voluntary and would be likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1] amends the table to section S2—2 in Schedule 2 by alphabetically inserting into the table:

- 'MPN' as a new unit of measurement; and
- 'most probable number' as the meaning of MPN.

'MPN' is a unit of measurement referred to in the new specification for jelly mushroom glycolipids (see subitem [2.2] below).

Item [2] amends Schedule 3 by including a specification for jelly mushroom glycolipids.

Subitem [2.1] inserts 'jelly mushroom glycolipids' and 'section S3—43' in the table to subsection S3—2(2), in alphabetical order. This table sets out the relevant provisions where specifications for the listed substances are set out in Schedule 3.

Subitem [2.2] inserts the actual specification for jelly mushroom glycolipids in Schedule 3.

Item [3] amends Schedule 8 by inserting 'jelly mushroom glycolipids' into each of the following tables to section S8—2:

- the table to section S8—2 entitled 'Food additive names—alphabetical listing' (alphabetically) (see subitem [3.1]); and
- the table to section S8—2 entitled 'Food additive names—numerical listing' (above the entry for 'Monk fruit extract or luo han guo extract') (see subitem [3.2]).

No INS number is prescribed as there is no current INS number for jelly mushroom glycolipids.

The effect of this amendment is that, for the purposes of subsection 1.2.4—7(1) of the Code, 'jelly mushroom glycolipids' must be listed in the statement of ingredients for a food in which jelly mushroom glycolipids is used as a food additive.

Item [4] amends the table to section S15—5 by inserting 'jelly mushroom glycolipids' and specified maximum permitted levels into the table for the following categories of beverages:

- subitem [4.1] - 100 mg/kg for Fruit and vegetable juices and fruit and vegetable juice products;
- subitem [4.2] - 50 mg/kg for Water based flavoured drinks;
- subitem [4.3] - 20 mg/kg for Formulated Beverages;
- subitem [4.4] - 10 mg/kg for Coffee, coffee substitutes, tea, herbal infusions and similar products;
- subitem [4.5] - 100 mg/kg for beer where the alcohol has been removed.

The effect of this amendment is to permit, for the purposes of Standard 1.3.1, the use of jelly mushroom glycolipids as a food additive in those categories of beverages at the specified maximum permitted levels.